

REMARKS***Specification Amendments***

As requested by the Examiner, the above amendment to the specification inserts the CROSS-REFERENCE TO RELATED APPLICATIONS on the first page of the specification. Priority to these applications has already been claimed, and the Examiner has acknowledged that a certified copy of the priority documents has been received in this National Stage application from the International Bureau.

Examiner-Initiated Interview

As the Examiner correctly notes in the Examiner-Initiated Interview Summary attached to the August 5, 2009 Action, the Examiner proposed a possible Examiner's Amendment to the claims that would overcome a proposed section 112, 1st paragraph "new matter" rejection. Specifically, the Examiner proposed deleting "multi-step batch" from the introductory portion of each of claims 51 and 52 and replacing it with the "one-pot" language from page 4 of the specification. The undersigned requested a non-final action wherein the proposed "new matter" rejection would be placed in writing; and giving applicants an opportunity to consider the "new matter" rejection and the Examiner's proposed claim amendment.

Claim Amendments

Applicants and the undersigned have now considered the Examiner's new matter rejection and the proposed amendment substituting "one-pot" for "multi-step batch" in claims 51 and 52 in view of the specification as a whole, the wording of claims 51 and 52 and the previous prior art rejections, and have determined that claims 51 and 52 accurately describe the invention in a manner that fully distinguishes over the prior art *without need for either the "multi-step batch" or the "one-pot" characterization*, as further discussed below. Accordingly, claims 51 and 52 have been further amended above to simply delete "multi-step batch" from the claims, thereby obviating the "new

matter” rejection in a manner that is not believed or intended to change the scope of the claims or their patentability over the prior art.

Claim Rejections - 35 USC § 112, 1st Paragraph - “New Matter”

The Examiner has rejected claims 51 and 52 under 35 U.S.C. 112, first paragraph “as failing to comply with the written description requirement,” specifically asserting that the claims contain the phrase “multi-step batch” which is “considered new matter as this phrase is found nowhere in applicants’ originally filed disclosure or claims.” This ground for rejection has been overcome by the deletion of the phrase “multi-step batch” from the introductory portion of both claims 51 and 52. It is therefore respectfully requested that this ground for rejection be withdrawn.

Withdrawal of Previous 35 USC § 103(a) Rejection

Applicants note with appreciation that the Examiner has withdrawn the prior rejection under 35 U.S.C. 103(a) on the basis of the amendments and arguments filed April 27, 2009.

The primary function of the April 27, 2009 amendments was to supplement the descriptions of the process steps in these claims with respect to the form and location of the various intermediates as they transitioned from one process step to another. In particular, these amendments made more clear that the intermediate (Formula IV) formed in step (a) is not isolated as such but is included in the resultant solution from step (a) that is acted upon in step (b); and that the intermediate (Formula V) that is formed in step (b) is not isolated as such but is included in the reaction mixture from step (b) that is acted upon in step (c) to form the compound of Formula II. Thus, as the Examiner notes in her Response to Amendment and Argument, “[t]he prior art references isolate the intermediate compounds used in the preparation of the formula II compound whereas the instant claims do not isolate the intermediates but continue onto the next step,” noting “[f]or example, wherein the instant formula IV is extracted as an organic phase and added to the polar solvent, the prior art isolates the formula IV.” (Action at page 2).

The phrase “multi-step batch” was inserted in the introductory portion of these claims by the April 27, 2009 amendments as a short-hand identifier of the process that is

detailed in the body of the claim, and this phrase did not itself further limit the claim. Therefore, removing this inserted phrase by the present amendments should not affect the scope of the claims and, in particular, should not alter the Examiner's conclusion that these claims are patentably distinct over the prior art. For this same reason, Applicants have not replaced this "multi-step batch" with the phrase "one-pot" as suggested by the Examiner. Although the term "one-pot" is used in the specification, the claims as amended April 27, 2009 already fully describe the combination of process steps that the specification associated with the phrase "one-pot," making it redundant. Moreover, it is thought that the insertion of the phrase "one-pot" could possibly lead to confusion if one tries to interpret that phrase literally as meaning that the entire process must be carried out in a single "pot" or reactor. The particular benefit and basis for patentability of the present process is not whether it can be carried out in fewer "pots," but rather that the need for the time consuming and costly isolation of certain of the intermediates has been avoided.

It is understood from the Examiner's Response to Amendment and Arguments as quoted in part above, that the basis for the determination of patentability of claims 51 and 52 over the prior art was that the "prior art references isolate the intermediate compounds used in the preparation of the formula II compound whereas the instant claims do not isolate the intermediates but continue into the next step." This distinction over the prior art is based on the detailed recitation of these process steps in the body of the claims, and does not depend on the introductory characterization of the process as being a "multi-step batch" process or a "one-pot" procedure.

It is therefore respectfully submitted that the claims as amended above overcome the "new matter" rejection, and remain patentable over the prior art as previously determined by the Examiner. Accordingly, withdrawal of the "new matter" rejection and the allowance of both claims are believed to be in order and are respectfully requested. However, should there be any issues remaining, it is respectfully requested that the Examiner telephone the undersigned to expedite the resolution thereof.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,
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